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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,468	04/12/2004	Sanford D. Altman	OAV-103XC1	4577

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary	Application No.	Applicant(s)	
	10/823,468	ALTMAN, SANFORD D.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 April 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/12/04, 11/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the ridges and spokes of the circle-C and double-D configurations of claims 18 and 19 must be shown or the feature(s) canceled from the claim(s). Furthermore, applicant must illustrate the placement of the catheter as set forth in claim 32. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 8, 24, 25, 27-31, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,718,678 to Fleming.

In the specification and figures, Fleming discloses the apparatus as claimed by applicant. In particular, Fleming discloses a multi-lumen catheter that may be used in a reverse flow direction (see column 5, lines 1-30). The catheter 10 has an inner lumen 22 created by tube 12 that defines an inner and outer surface of lumen 22 that may be used as an intake or arterial lumen (see column 5, lines 1-11). The catheter further comprises a second, outer lumen 40 defined by tube 26 that defines an inner and outer surface of lumen 40, and the second lumen may be used for return or venous flow. The distal end 20 of lumen 22 terminates at the distal end 24 of catheter 10, with is beyond the distal end 38 of outer, venous lumen 40. Inner arterial lumen 22 comprises at least apertures 70, 72 and outer venous lumen comprises apertures 68 (see column 8, lines 58-67, column 9, lines 1-4).

With regard to claim 2, Fleming discloses and illustrates that the inner and outer lumens are disposed in a coaxial configuration (see column 5, lines12-13, FIGS 3, 4, 5A).

With regard to claim 8, Fleming illustrates that the distal end 38 of the outer or venous lumen 40 is connected to the outer surface (tube 12) of inner or arterial lumen 22 (see FIG 5A). Examiner considers this connection to correspond to applicant's claim that the lumen and outer surface are "fused," meeting the limitations of the claims.

With regard to claims 24 and 25, Fleming discloses that the distal end of the venous or outer lumen 40 comprises a plurality of circular apertures 68 (see FIGS 1, 5A, column 8, lines 15-32).

With regard to claims 27 and 28, Fleming discloses that the catheter 10 may be formed of biocompatible polymers such as polyurethanes and PTFE, and may be reinforced with barium sulfate, a metal, meeting the limitations of the claim (see column 5, line 56 through column 6 line 51).

With regard to claim 29, the catheter 10 comprises a hub 74 with lumens therethrough (rendering it hollow). The inner and outer lumens are independent and movable with respect to each other, indicating that the lumens are separable from one another, meeting the limitations of the claim (see column 9, lines 16-30).

With regard to claim 30, applicant claims the intended placement of the catheter in a patient's vasculature. Such limitations are considered by the examiner to be a statement of the intended use of the catheter. It has been held that a recitation with respect to the manner in which a claimed is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Fleming specifically discloses that his catheter is designed to be employed in a patient's vasculature (see

column 1, lines 11-13), indicating that it is capable of being placed in the location claimed by applicant, thereby meeting the limitations of the claim.

With regard to claims 31, 33, and 35, Fleming discloses that the catheter may be deployed in a manner well-known in the art. In particular, vessels (such as the jugular or subclavian veins) are cannulated by perforating the vessel with a needle, passing a guidewire through the needle, and inserting a catheter over the guidewire into the blood vessel (see column 1, lines 11-55). The catheter may then be used to draw blood through an arterial lumen to a blood treatment device that treats the blood and then return treated blood to the patient (see column 1, lines 35-38). Fleming specifically discloses that the catheter 10 is designed for hemodialysis treatment, indicating that the claimed catheter is used in the procedure described as common in the art (see column 51-55). Since Fleming discloses the catheter as claimed by applicant and the blood treatment method claimed by applicant, the Fleming disclosure meets the limitations of the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,718,678 to Fleming.

In the specification and figures, Fleming discloses the apparatus substantially as claimed (see rejection above) with the exception of the distance between the ends of the inner and outer lumens. Fleming discloses that opening 72 is about 17-20 mm from venous openings 68, which are located near the distal end of venous lumen 40 (see column 9, lines 1-4). However, Fleming further discloses that the length of the tubes 12, 26, that define inner and outer lumens may be varied in accordance with the intended application and vessel size (see column 6, lines 45-52). Such a disclosure sets up tube size as a result-effective variable that comprises an optimum value depending on the desired application. It has been held that discovering an optimum value of a result-effective variable involves only routine skill in the art. See MPEP 2144.05. In the instant case, it would have been obvious to form catheter disclosed by Fleming to have the dimensions claimed by applicant, since Fleming discloses that the length of the tubes that make up the catheter are a result-effective variable from which an operator may select an optimum value depending on the intended application.

6. Claims 6-7 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,718,678 to Fleming in view of US 6,595,966 to Davey et al.

In the specification and figures, Fleming discloses the device substantially as claimed by applicant (see rejection above) with the exception of a tapered distal end of the lumens and a therapeutic agent.

With regard to claims 6-7, Davey discloses a catheter that tapers from proximal end 11 to distal end 15 (see FIG 1A, column 6, lines 37-40). Davey teaches that the design may apply to multilumen catheters and minimizes the pressure drop across the

catheter, maximizing flow rate through the catheter and minimizing trauma to the fluid flowing through it (see column 4, lines 43-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the multilumen catheter disclosed by Fleming with lumens tapering towards the distal end as disclosed by Davey in order to maximize fluid flow while minimizing fluid trauma, as taught by Davey.

With regard to claim 26, Davey discloses that a surface of the conduit may be treated with heparin, an anticoagulant, in order to prohibit deposit of materials on the surface of the conduit (see column 2, lines 25-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the catheter disclosed by Fleming with a therapeutic agent such as an anticoagulant as disclosed by Davey in order to prevent deposit of materials on the surface of the conduit, as taught by Davey.

7. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,718,678 to Fleming in view of US 5,167,623 to Cianci et al.

In the specification and figures, Fleming discloses the device substantially as claimed by applicant (see rejection above) with the exception of the circle-C configuration and the distance between the ends of the inner and outer lumens.

With regard to claim 11, Fleming discloses that circle-C catheters are well-known in the art (see column 1, lines 44-50). Cianci discloses a multilumen catheter that features an inner and outer lumen disposed within a circle-c configuration in order to reduce the cross-section of the catheter so that it may be inserted in a patient without

the use of a dilator (see column 1, lines 22-37). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the catheter disclosed by Fleming in a circle-c configuration as disclosed by Cianci in order to reduce the cross-sectional size of the catheter, as taught by Cianci.

With regard to claims 12-14, Fleming discloses that opening 72 is about 17-20 mm from venous openings 68, which are located near the distal end of venous lumen 40 (see column 9, lines 1-4). However, Fleming further discloses that the length of the tubes 12, 26, that define inner and outer lumens may be varied in accordance with the intended application and vessel size (see column 6, lines 45-52). Such a disclosure sets up tube size as a result-effective variable that comprises an optimum value depending on the desired application. It has been held that discovering an optimum value of a result-effective variable involves only routine skill in the art. See MPEP 2144.05. In the instant case, it would have been obvious to form catheter disclosed by Fleming to have the dimensions claimed by applicant, since Fleming discloses that the length of the tubes that make up the catheter are a result-effective variable from which an operator may select an optimum value depending on the intended application.

With regard to claim 17, Fleming illustrates that the distal end 38 of the outer or venous lumen 40 is connected to the outer surface (tube 12) of inner or arterial lumen 22 (see FIG 5A). Examiner considers this connection to correspond to applicant's claim that the lumen and outer surface are "fused," meeting the limitations of the claims.

8. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,718,678 to Fleming in view of US 5,167,623 to Cianci et al, further in view of US 6,206,849 to Martin et al.

In the specification and figures, Fleming and Cianci disclose the device substantially as claimed by applicant (see rejection above) with the exception of ridges or spokes between the inner and outer lumens. Examiner considers the ridge and the spoke claimed by applicant to be substantially similar, since all the limitations of the claimed spoke are part of the claimed ridge (that is, a ridge may function as a spoke). Martin discloses a dialysis catheter with outer lumens 50, 52, and inner lumen 54 that are connected by ridges or spokes 48 that run substantially along the length of the catheter such that they form separate outer lumens 50, 52 (see FIG 3, column 5, lines 37-50). Both the ridges and spokes claimed by applicant read on the ridges or spokes 48 disclosed by Martin, meeting the limitations of the claims. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use ridges or spokes as disclosed by Martin in the catheter disclosed by Fleming and Cianci in order to create additional lumens, as taught by Martin.

9. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,718,678 to Fleming in view of US 5,167,623 to Cianci et al, further in view of US 6,595,966 to Davey.

In the specification and figures, Fleming and Cianci disclose the device substantially as claimed by applicant (see rejection above) with the exception of a tapered distal end of the lumens. Davey discloses a catheter that tapers from proximal

end 11 to distal end 15 (see FIG 1A, column 6, lines 37-40). Davey teaches that the design may apply to multilumen catheters and minimizes the pressure drop across the catheter, maximizing flow rate through the catheter and minimizing trauma to the fluid flowing through it (see column 4, lines 43-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the multilumen catheter disclosed by Fleming and Cianci with lumens tapering towards the distal end as disclosed by Davey in order to maximize fluid flow while minimizing fluid trauma, as taught by Davey.

10. Claims 9, 10, and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,718,678 to Fleming in view of US 6,206,849 to Martin et al.

In the specification and figures, Fleming discloses the device substantially as claimed by applicant (see rejection above) with the exception of ridges or spokes between the inner and outer lumens and a double-D configuration.

With regard to claims 9 and 10, Examiner considers the ridge and the spoke claimed by applicant to be substantially similar, since all the limitations of the claimed spoke are part of the claimed ridge (that is, a ridge may function as a spoke). Martin discloses a dialysis catheter with outer lumens 50, 52, and inner lumen 54 that are connected by ridges or spokes 48 that run substantially along the length of the catheter such that they form separate outer lumens 50, 52 (see FIG 3, column 5, lines 37-50). Both the ridges and spokes claimed by applicant read on the ridges or spokes 48 disclosed by Martin, meeting the limitations of the claims. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use

ridges or spokes as disclosed by Martin in the catheter disclosed by Fleming in order to create additional lumens, as taught by Martin.

With regard to claim 20, Fleming discloses that double-D catheter configurations are well-known in the art (see column 1, lines 40-43). Martin discloses a multiple lumen catheter with a double-D configuration for the withdrawal and return lumens (see column 9 lines 30-40, FIG 15). The configuration reduces the ratio between the cross-sectional area of the extraction and return lumens and the cross-sectional area of the catheter (see column 9, lines 30-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the catheter disclosed by Fleming in the double-D configuration disclosed by Martin in order to reduce the ratio of the cross sectional area of the withdrawal and return lumens to the cross sectional area of the catheter, as taught by Martin.

With regard to claims 21-23, Fleming discloses that opening 72 is about 17-20 mm from venous openings 68, which are located near the distal end of venous lumen 40 (see column 9, lines 1-4). However, Fleming further discloses that the length of the tubes 12, 26, that define inner and outer lumens may be varied in accordance with the intended application and vessel size (see column 6, lines 45-52). Such a disclosure sets up tube size as a result-effective variable that comprises an optimum value depending on the desired application. It has been held that discovering an optimum value of a result-effective variable involves only routine skill in the art. See MPEP 2144.05. In the instant case, it would have been obvious to form catheter disclosed by Fleming to have the dimensions claimed by applicant, since Fleming discloses that the length of the

tubes that make up the catheter are a result-effective variable from which an operator may select an optimum value depending on the intended application.

11. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,718,678 to Fleming in view of US 6,620,118 to Prosl et al.

In the specification and figures, Fleming discloses the method substantially as claimed by applicant (see rejection above) with the exception of placing the suction or arterial line in communication with the right atrium and the return or venous line in communication with the superior vena cava. However, Prosl discloses a catheter and method for performing dialysis that places a suction or arterial port 225 in the patient's right atrium 70 and the return line 230 in the patient's superior vena cava 45 (see column 25, lines 1-45). Such a placement prevents "short circuiting" of clean blood through the catheters and reduces the likelihood that the suction line will be occluded by the vessel walls (see column 25, lines 15-35). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the insertion method disclosed by Fleming to position the catheter disclosed by Fleming in the location disclosed by Prosl in order to reduce short-circuiting and suction tube occlusion, as taught by Prosl.

12. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,718,678 to Fleming in view of US 6,719,749 to Schweikert et al.

In the specification and figures, Fleming discloses the method substantially as claimed by applicant including the hub and separable tubes (see rejection above) with the exception of removing the catheter from the vessel and replacing the arterial lumen.

However, Schweikert discloses a multilumen catheter with removable tubes that allow one tube to be replaced independently of another (see column 2, lines 23-25). Schweikert further discloses that the entire catheter assembly may be replaced in the event of a blockage (see column 7, lines 50-59). In order to replace the catheter assembly, one must necessarily remove the first catheter from the patient's vessel. Similarly, the process of replacing the original catheter with a new one necessarily includes replacing the original lumens with new ones, meeting the limitations of applicant's claim drawn to replacing a particular lumen of the catheter. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the step of removing and replacing a defective catheter, as disclosed by Schweikert, to the method of catheter placement disclosed by Fleming, in order to restore flow through the defective lumens, as taught by Schweikert (see column 2, lines 23-27).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

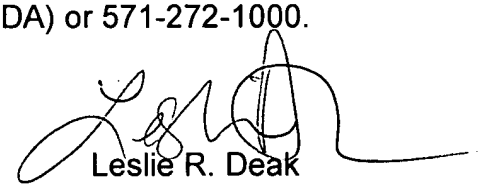
a. US 6,758,836 Zawacki

i. Multilumen dialysis catheter

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
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Art Unit 3761
15 September 2006